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FOLEY AND LARDNER LLP  
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WASHINGTON, DC 20007

EXAMINER
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MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/700,314

Applicant(s)

GUEGLER ET AL.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 63-74 is/are pending in the application.
- 4a) Of the above claim(s) 70 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63-69 and 72-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/28/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I (claims 63-69, 72-74) on 9/6/05 is acknowledged. Claims 1-62 have been canceled and new claims 62-74 (8/15/2005) have been added. Applicants have traversed the restriction requirement based on the argument that claims 70-71 are drawn to a method of treatment with an the antibody to the chemoattractant protein and that examination of the method and product claims together would not be undue burden on the Examiner. However, contrary to Applicants arguments, only once the elected product claims 63-69, 72-74 are allowable, the method claims 70-71 will be rejoined with the allowable product claims (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995), in which a new, unobvious material is used in a known process). Ochiai determined that a process was free of the prior art if it employed a product which was free of the prior art. However, only if the product claims of Group I (claims 63-69, 72-74) are found allowable, the subject matter of Group I will be rejoined with the process claims 70-71, only if the process claims are of the same scope as the allowable product claims.

Claims 63-69, 72-74 are under consideration by the Examiner.

### ***Specification***

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite "antibodies to a chemokine expressed in inflamed adenoid".

### ***Claim Rejections - 35 USC § 112, first paragraph-new matter***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 63-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite "...human antibody" which language is new matter in the claims, since the instant specification fails to disclose this limitation. The specification fails to provide proper support for this language in the claims for the following reason:

Page 10, lines 25-35, discloses:

"Antibodies specific for ADEC may be produced by inoculation of an appropriate animal with the polypeptide or an antigenic fragment. An antibody is specific for ADEC if it is produced against an epitope of the polypeptide and binds to at least part of the natural or recombinant protein. Induction of antibodies includes not only the stimulation of an immune response by injection into animals, but also analogous steps in the production of synthetic antibodies or other specific-binding molecules such as the screening of recombinant immunoglobulin libraries (cf. Orlandi R et al (1989) Proc Natl Acad Sci USA 86:3833-3837, or Huse WD et al (1989) Science 256:1275-1281) or the in vitro stimulation of lymphocyte populations. Current technology (Winter G and Milstein C (1991) Nature 349:293-299). provides for a number of highly specific binding reagents based on the principles of antibody formation. These techniques may be adapted to produce molecules specifically binding ADEC."

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Furthermore, pages 16-17 disclose production of ADEC-Specific antibodies and Diagnostic Test Using ADEC-Specific Antibodies.

However, the instant claims encompass "human antibody". The specification does not disclose the "human antibody" as recited in the claims. The limitation as disclosed in the specification is not equivalent to the specific limitation recited in the claims. This rejection can only be obviated by deleting the recitation of "human" and reciting the specific limitation for which there is support in the instant specification.

Similarly, claim 63, sub-part (a) recites "...polypeptide consisting essentially of the amino acid sequence of ...." which language is new matter in the claim, since the instant specification fails to disclose this limitation. The specification fails to provide proper support for this language in the claim. This rejection can only be obviated by deleting the recitation of the limitation "polypeptide consisting essentially of.." from the claims.

Claim 63, sub-part (b) recites "...polypeptide consisting essentially of naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2...." which language is new matter in the claim, since the instant specification fails to disclose this limitation. The specification fails to provide proper support for this language in the claim. This rejection can only be obviated by deleting the recitation of this limitation from the claims.

Claim 63, sub-part (c) recites "...fragment consisting essentially of at least 9 contiguous amino acids of a polypeptide consisting of the amino acid sequence of SEQ ID NO:2...." which language is new matter in the claim, since the instant specification fails to disclose this

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limitation. The specification fails to provide proper support for this language in the claim. This rejection can only be obviated by deleting the recitation of this limitation from the claims.

3b. Claims 63-69, 72-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:2 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims drawn to an antibody to “a naturally occurring amino acid sequence at least 90% identical to... SEQ ID NO:2” as recited in claim 11(b).

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Rieger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a

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gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:2, the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for variants of the chemokine polypeptide is provided in the specification on page 5, lines 1-6. However, no disclosure, beyond the mere mention of variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim

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Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an antibody to an isolated polypeptide molecule comprising the amino acid sequence set forth in SEQ ID NO:2 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

The claims are drawn to a polypeptide having at least 90% identity to a particular disclosed sequence (SEQ ID NO:2). The claims do not require that the polypeptide possess any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that are defined only by sequence identity. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved for the recited biological activity of chemotactic activity or ability to activate neutrophils or monocytes. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics and structure/function relationship, the specification does not provide adequate written description of the claimed genus.

3c. Claims 63-69, 72-74, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody which specifically binds a protein



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consisting of the amino acid sequence set forth in SEQ ID NO:2 does not reasonably provide enablement for an isolated antibody to a protein consisting essentially of a naturally occurring amino acid sequence at least 90% identical to SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 63 (b), is overly broad in the recitation of "at least 90% identical to an amino acid sequence of SEQ ID NO:2" since no guidance is provided as to which of the myriad of antibody sequences to polypeptide species encompassed by the claim will retain the desired characteristics. Applicants disclose that variants of the polypeptide can be generated by conservative or nonconservative changes, including amino acid deletions, substitutions and insertions, without disclosing any actual or prophetic examples on expected performance parameters of any of the possible muteins of SEQ ID NO:2 (page 5, lines 1-6). There is no guidance provided in the specification as to how one of ordinary skill in the art would generate an antibody to a polypeptide other than that exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use

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the invention based on the content of the disclosure. Given the breadth of the claim in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

Claim 63 is overly broad in its limitation of "at least 90% identity" because no guidance is provided as to which of the myriad of claimed antibodies to the polypeptides will retain the desired characteristics. Variants of a nucleic acid can be generated by deletions, insertions, and substitutions of nucleotides, but no actual or prophetic examples on expected performance parameters of any of the possible variants of the protein molecule have been disclosed. Furthermore, it is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. For example, Mikayama et al. (1993) teaches that the human glycosylation-inhibiting factor (GIF) protein differs from human migration inhibitory factor (MIF) by a single amino acid residue (page 10056, Figure 1). Yet, despite the fact that these proteins are 90% identical at the amino acid level, GIF is unable to carry out the function of MIF, and MIF does not exhibit GIF bioactivity (page 10059, second column, third paragraph). It is also known in the art that a single amino acid change in a protein's sequence can drastically affect the structure of the protein and the architecture of an entire cell. Voet et al. (1990) teaches that a single Glu to Val substitution in the beta subunit of hemoglobin causes the hemoglobin molecules to associate with one another in such a manner that, in homozygous individuals, erythrocytes are altered from their normal discoid shape and assume the sickle shape characteristic of sickle-cell anemia, causing hemolytic

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anemia and blood flow blockages (pages 126-128, section 6-3A and page 230, column 2, first paragraph).

There is no guidance provided in the instant specification as to how one of skill in the art would generate and use an antibody to a polypeptide having at least 90% to an amino acid sequence of SEQ ID NO:2 other than to an antibody to a polypeptide of SEQ ID NO:2 exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

3d. Claims 63-69 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody which specifically binds a protein consisting of the amino acid sequence set forth in SEQ ID NO:2, does not reasonably provide enablement for an isolated antibody which specifically binds to a polypeptide "consisting essentially of" the amino acid sequence set forth in SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

With respect to claim 63, the specification does not enable an antibody to a protein "consisting essentially of..." the amino acid sequence set forth in SEQ ID NO:2. The specification does not enable the skilled artisan to make and/or use antibodies to polypeptides that have essentially the same amino acid sequence as the one disclosed. The issue here is how substantial must the sequence identity be, and what amino acids constitute this identity? The specification does not teach which residues can be conservatively substituted without affecting the functional activity of the receptor protein. It is known to the skilled artisan that conservative amino acid substitutions outside of the active site of a protein will not affect the functional activity of the protein; however, amino acid substitutions, even conservative alterations, within

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the active site can inactivate the protein or change its functional activity. Absent the specific degree of sequence identity, it is unpredictable if the protein would also possess the same activity as the polypeptide having the amino acid sequence of SEQ ID NO:2. Thus, without guidance as to which residues can be conservatively substituted, the skilled artisan would not be able to make and/or use antibodies to polypeptides consisting essentially of the amino acid sequence as the polypeptide of amino acid sequence of SEQ ID NO:2.

There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a G-CSF polypeptide other than the ones exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims, in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

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With respect to claim 63, as recited, the claim broadly encompasses an antibody to all "epitopes" of the polypeptide of SEQ ID NO:2. The specification is only enabling for antibodies to the entire polypeptide, which polypeptide comprises epitope-bearing portions but is non-enabling for the full scope of the embodiments claimed.

The specification, on page 5, lines 18-21 recites that:

"A polypeptide "fragment" "portion," or "segment" is a stretch of aa residues of at least about 5 amino acids, often at least about 7 aa, typically at least about 9 to 13 aa, and, 20 in various embodiments, at least about 17 or more aa. To be active, ADEC polypeptide must have sufficient length to display biologic and/or immunologic activity."

Claim 63© recites that the claimed antibody binds a fragment which has chemotactic activity or is able to activate neutrophils or monocytes.

Furthermore, Harlow et al. teach peptides of six residues in length will consistently elicit antibodies that bind to the original protein (page 76, lines 22-23 in particular). The claims as written encompass "fragments" of the polypeptide which limitation is non-enabled by the specification in the absence of reference to a subset of amino acid sequences comprising the domain to which the functional properties of the polypeptide have been ascribed. The specification provides no guidance as to which amino acids might comprise the minimum residues of an epitope-bearing fragment, which retains any enabled functional property peculiar to the instant chemokine. One would not have a reasonable expectation of successfully making a representative number of fragments having biological activity, consistent with the scope of the claims. Additionally, one would reasonably expect that fragmentation of a 109 amino acid

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polypeptide would abolish activity because activity is determined not only by primary sequence, but also by three-dimensional structure, as, for example, is the case for the ligand binding site of a receptor or for a catalytic site of an enzyme. Therefore, in the absence of delimiting amino acid sequences that make up the functional domain(s) of the instant chemokine, a person of ordinary skill in the art would be unable to make antibodies to fragments of the polypeptide of SEQ ID NO:2, without undue experimentation to determine which epitope-bearing fragment or portion has the desirable biological activity. For this reason it would require undue experimentation to determine which epitope-bearing portion of the polypeptide has biological activity, a requisite property for the practice of the invention commensurate in scope with the claimed antibodies.

***Claim Rejections - 35 USC § 112, second paragraph***

4. Claims 63-69, 72-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 is vague and indefinite for several reasons.

Claim 63 is vague and indefinite because the metes and bounds of the limitation "consisting essentially of amino acid sequence" is undeterminable. Either a protein has that amino acid sequence or it doesn't. If this limitation is intended to encompass a protein having other than the recited amino acid sequence, as implied by the presence of the word "essentially", it is unclear how far an amino acid sequence can deviate from the recited amino acid sequence and still be encompassed by the claims.

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Claim 63 is indefinite in the recitation of the term "naturally occurring". It is unclear whether this term imposes a required limitation on the claim, such that it only encompasses, for example, antibodies to polypeptide molecules obtained from nucleic acid molecules amplified from cDNA or all nucleic acid molecules that encode the polypeptide. Therefore, the metes and bounds of the claim are unclear.

Claim 63, line 3, is vague and indefinite because it recites "SEQ ED NO:2" rather than "SEQ ID NO:2".

Claim 63, line 6, is vague and indefinite because it recites "ammo acid" rather than "amino acid".

Claim 63, is vague and indefinite because it recites "...is able to activate neutrophils or monocytes" rather than "activates neutrophils or monocytes".

Claim 67 recites the limitation "an antibody of claim 63" in line 3, rather than "the antibody of claim 63". There is insufficient antecedent basis for this limitation "an antibody" in the claim.

Claims 64-66, 68-69, 72-74 are rejected as vague and indefinite insofar as they depend on the above claim for their limitations.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 63, 66-67, are rejected under 35 U.S.C. 102(b) as being anticipated by Osawa et al (U.S. Patent No. 5,126,434).

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The reference teaches a monoclonal antibody to a peptide having macrophage chemotactic activity (see column 1, lines 8-13). The instant claims encompass an antibody to a fragment consisting "essentially of..." the amino acid sequence of SEQ ID NO:2 wherein the fragment has chemotactic activity. In the absence of a definition for the term "consisting essentially of", the protein of the prior art meets the limitations of a protein that has chemotactic activity and the antibody of the prior art meets the limitations of an antibody to a fragment consisting "essentially of..." the amino acid sequence of SEQ ID NO:2 wherein the fragment has chemotactic activity.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).



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Claims 63, 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osawa et al (U.S. Patent No. 5,126,434) as applied to claims 63, 66-67 above, and further in view of Hart (U.S. Patent No. 5,094,941).

Osawa teaches an antibody to a chemotactic protein (see paragraph 5 above) except that Osawa does not explicitly teach the labeled antibody.

Hart teaches a means of labeling antibodies with radioisotopes or imaging agents and enzymes (as conjugates) for diagnostic purposes (including combinations with pharmaceutical carriers for administration of labeled material) or for use in assay methods, respectively (at column 13, paragraphs 2 and 3, lines 25-61). Hart does not explicitly teach a means to label antibody against KLH, however, Craig discloses that measurement and detection of a hapten such as KLH is important in a wide variety of immunoassay formats. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the antibody of Osawa in view of Hart by labeling antibodies by the method of Hart because labeled antibody administration coupled with radiographic analysis (imaging) is useful for quantitation of haptens.

### ***Conclusion***

Claims 63-69, 72-74 are rejected.

### ***Advisory Information***

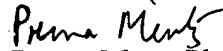
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

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Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
October 5, 2005